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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,987	02/04/2004	Pawan Seth	1259-001/CPB	3583

27572 7590 10/26/2007

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EXAMINER	
PERREIRA, MELISSA JEAN	
ART UNIT	**PAPER NUMBER**
1618	
MAIL DATE	**DELIVERY MODE**
10/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/771,987	SETH ET AL.	
	Examiner	Art Unit	
	Melissa Perreira	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-120* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-120* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 October 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-120 are pending in the application. Any objections and/or rejections from previous office actions that have not been reiterated in this office action are obviated.

Response to Arguments

1. Applicant's arguments filed 10/12/07 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1,2,6-18,20,22,29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Moeckel et al. (US 5,955,106) as stated in the office action mailed 5/25/07.

4. Applicant asserts that Moeckel et al. does not teach of an immediate release core and does not provide for a coating "achieving ...extended release of... metformin".

5. In regards to the instant claim 1, the tablet core of Moeckel et al. comprise metformin hydrochloride in about 70-95% and pharmaceutically acceptable excipients,

therefore it encompasses the core of the instant claim 1. There is no added component, structural characteristic, etc. to the core to distinguish it as immediate release or distinguish it over the core of the prior art. The coating of Moeckel et al. surrounds the core and is permeable to metformin and therefore it encompasses the coating of the instant claim 1.

6. In regards to claim 22, the core of Moeckel et al. also contains a hydrophilic swelling substance/expanding agent. Again the core of Moeckel et al. encompasses the core of the instant claim 22 which includes an expanding agent. There is no added component, structural characteristic, etc. to the core to distinguish it as immediate release or distinguish it over the core of the prior art.

7. In regards to claim 2, the coating of Moeckel et al. comprises a water-insoluble, water-permeable film-forming polymer (ethyl cellulose); a water-soluble polymer (polyvinylpyrrolidone) and a plasticizer (stearic acid) and therefore encompasses the coating of the instant claim 2.

8. The recitation of "tablet achieving said extended release of said metformin by the design of said coating" is a product-by-process limitation. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

9. The extended release pharmaceutical tablet of the disclosure encompasses the extended release pharmaceutical tablet of the instant claims and should therefore be capable of the same functions and have the same properties, such as the dissolution profile.

10. Claims 1-4,6-14,16-22,28-32,34-42,44-50 and 56-58 are rejected under 35 U.S.C. 102(e) as being anticipated by Seth (US 6,350471B1) as stated in the office action mailed 5/25/07.

11. Applicant asserts that Seth does not teach or suggest a core containing metformin but that a mere reference stating, "the cores are coated with a coating designed to achieve a controlled release of metformin", is not by itself a teaching that the cores contain metformin.

12. Seth explicitly states, "the tablet cores are then coated with the semi-permeable coating designed to achieve a controlled release of metformin" (column 2, lines 26-28). It is anticipated by this statement that cores of the disclosure contain metformin.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 1,2,4-18,20,22-27,29-31,33-46,48,50-55,57-59,61-73,75,77-81,83,85,87-99,101,103-106 and 108-112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moeckel et al. (US 5,955,106) in view of Buhler et al. (US 6,592,900B1) and/or Remington's Pharmaceutical Sciences **1990** 18th Ed. Chpt. 89, p1637 as stated in the office action mailed 5/25/07.

15. Applicant asserts that Moeckel et al. does not teach of an immediate release core and does not provide for a coating "achieving ...extended release of... metformin".

16. In regards to the instant claims 1,31 and 59 the tablet core of Moeckel et al. comprise metformin hydrochloride in about 70-95% and pharmaceutically acceptable excipients, therefore it encompasses the core of the instant claims 1,31 and 59. There is no added component, structural characteristic, etc. to the core to distinguish it as immediate release or distinguish it over the core of the prior art. The coating of Moeckel et al. surrounds the core and is permeable to metformin and therefore it encompasses the coating of the instant claims 1.

17. In regard to the instant claims 22 and 85, the core of Moeckel et al. also contains a hydrophilic swelling substance/expanding agent. Again the core of Moeckel et al. encompasses the core of the instant claims 22 and 85 which includes an expanding agent. There is no added component, structural characteristic, etc. to the core to distinguish it as immediate release or distinguish it over the core of the prior art.

18. In regards to the instant claim 110, the core of Moeckel et al. also contains a hydrophilic swelling substance/expanding agent. In combination with the reference of Buhler et al. it would have been obvious to one ordinarily skilled in the art to utilize/try

polyvinylpyrrolidone or its equivalent, crospovidone, as a disintegrant/expanding agent for a tablet preparation.

19. In regards to claims 2,31,59,85 and 110 the coating of Moeckel et al. comprises a water-insoluble, water-permeable film-forming polymer (ethyl cellulose); a water-soluble polymer (polyvinylpyrrolidone) and a plasticizer (stearic acid) and therefore encompasses the coating of the claims 2,31,59,85 and 110. It is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

20. The recitation of "tablet achieving said extended release of said metformin by the design of said coating" is a product-by-process limitation. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

21. The extended release pharmaceutical tablet of the disclosure encompasses the extended release pharmaceutical tablet of the instant claims and should therefore be

capable of the same functions and have the same properties, such as the dissolution profile.

22. Claims 1-14,16-42,44-69,71-95 and 97-120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seth (US 6,350,471B1) in view of Buhler et al. (US 6,592,900B1) and/or Remington's Pharmaceutical Sciences **1990** 18th Ed. Chpt. 89, p1637 as stated in the office action mailed 5/25/07.

23. Applicant asserts that Seth does not teach or suggest a core containing metformin but that a mere reference stating, "the cores are coated with a coating designed to achieve a controlled release of metformin", is not by itself a teaching that the cores contain metformin.

24. Seth explicitly states, "the tablet cores are then coated with the semi-permeable coating designed to achieve a controlled release of metformin" (column 2, lines 26-28). It is anticipated by this statement that cores of the disclosure contain metformin.

25. At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize use polyvinylpyrrolidone or its equivalent, crospovidone, as a disintegrant/expanding agent for a tablet preparation (Buhler et al). Also sodium starch glycolate is a well-known and commonly used disintegrants/expanding agent for tablet preparations (Remington's). One would have a reasonable expectation of success for substituting the polyvinylpyrrolidone contained in the core of the extended release tablet of Seth for the crospovidone or sodium starch glycolate.

New Grounds of Rejection Necessitated by the Amendment

Claim Rejections - 35 USC § 112

26. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

27. Claims 1,31,59,85 and 110 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The term "expanding agent" in the specification is very broad and therefore does not necessarily impart the immediate release property to the core of the tablet.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

28. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

29. Claims 1,22,29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Cheng et al. (US 6,099,859).

30. Cheng et al. (US 6,099,859) teaches of an extended release pharmaceutical tablet that contains a core of metformin hydrochloride in about 50-98% or 75-95% (850 mg) (column 3, lines 39 and 66+; column 5, lines 35-41; example 3), a binder (i.e. polyvinylpyrrolidone) in about 0-40% (column 3, lines 40-41 and 48) coated by a semipermeable membrane in about 50-99% (column 4, lines 11,29 and 58). The semipermeable membrane may consist of polymer(s) (i.e. cellulose ethers, hydroxypropyl methylcellulose, polyvinyl alcohol, cellulose acetate, hydroxypropyl cellulose) and a plasticizer (i.e. stearate or dibutylsebacate in about 0-25% (column 4, lines 40 and 61; column 5, line 3; column 6, line 56) and have a hole/passageway for the release of the antihyperglycemic drug (column 5, lines 8-12). The dissolution of the tablet provides for treatment over a twelve to twenty-four hour period (column 2, lines 16-21; column 5, lines 51-57; column 7, lines 13-18). The extended release pharmaceutical tablet of the disclosure encompasses the extended release pharmaceutical tablet of the instant claims and should therefore be capable of the same functions and have the same properties, such as the dissolution profile.

Claim Rejections - 35 USC § 103

31. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

32. Claims 1,2,4-27,29-31,33-55,57-59,61-81,83-85,87-106 and 108-112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. (US 6,099,859) in view of Moeckel et al. (US 5,955,106) and further in view of Buhler et al. (US 6,592,900B1) and/or Remington's Pharmaceutical Sciences **1990** 18th Ed. Chpt. 89, p1637.

33. Cheng et al. (US 6,099,859) discloses an extended release pharmaceutical tablet that contains a core of metformin hydrochloride in about 50-98% or 75-95% (850 mg) (column 3, lines 39 and 66+; column 5, lines 35-41; example 3), a binder (i.e. polyvinylpyrrolidone) in about 0-40% (column 3, lines 40-41 and 48) coated by a semipermeable membrane in about 50-99% as well as that stated above. Cheng et al. does not disclose the tablet coating containing a water-insoluble, water-permeable film-forming polymer.

34. Moeckel et al. (US 5,955,106) discloses an extended release pharmaceutical tablet that contains metformin hydrochloride in about 70-95% (i.e. 850 mg) (column 1, lines 8-13; column 2, lines 23-24), hydrophilic swelling/expanding substances (i.e. polyvinyl alcohol or polyvinylpyrrolidone, hydroxypropyl methylcellulose, etc.) (column 1, lines 20-30), a film former (i.e. ethyl cellulose, methylhydroxypropyl cellulose) (column 1, lines 55-57 and 67; column 2, lines 5-6; column 4, line 2). The coating/film may comprise ethyl cellulose, flow regulating agents (i.e. silicon dioxide and stearic acid) and a binding agent (i.e. polyvinylpyrollidone) (column 2, line 35 and 48). The core of the tablet contains the metformin, the expanding substance and magnesium stearate (stearic acid) which is coated with the film via the standard coating process (column 5,

lines 13-14; example 1). The controlled release of metformin from the tablets of the disclosure should be over a time period of 0.5-10 hours (column 5, lines 31-33).

35. Buhler et al. (US 6,592,900B1) discloses the use of crospovidone/polyvinylpyrrolidone as a disintegrant for tablets whereas crospovidone is particularly suitable for this (column 3, lines 24-26; column 2, lines 42-43).

36. Remington's Pharmaceutical Sciences **1990** 18th Ed. Chpt. 89, p1637 discloses crospovidone and sodium starch glycolate as well known and commonly used disintegrants/expanding agents for tablet preparations. Sodium starch glycolate is known to swell seven- to twelvefold in all three dimensions in less than 30 sec. The disintegrating agent is mixed with the active agent and diluents prior to granulation (p37, paragraph 7,8 and 10).

37. At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize/try the film/coating of Moeckel et al. to coat the metformin tablets of Cheng et al. as both disclosures are drawn to controlled release formulations containing metformin. The result would be the preparation of a controlled release formulations containing metformin and would be predictable. Also, the use of polyvinylpyrrolidone or its equivalent, crospovidone, as a disintegrant/expanding agent for a tablet preparation (Buhler et al) would be obvious and give predictable results. Sodium starch glycolate is also a well-known and commonly used disintegrants/expanding agent for tablet preparations (Remington's). One would have a reasonable expectation of success for substituting the polyvinylpyrrolidone contained in the core of the extended release tablet of Cheng et al. for the crospovidone or sodium starch glycolate.

38. The extended release pharmaceutical tablet of the disclosure encompasses the extended release pharmaceutical tablet of the instant claims and should therefore be capable of the same functions and have the same properties, such as the dissolution profile. Furthermore, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP
October 18, 2007

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER